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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
PORTLAND DIVISION

NANCY DOTY, INC. as CONSERVATOR FOR KYLI JOHNSON, a minor,

Plaintiff,

vs.

ABBOTT LABORATORIES, and ABBOTT LABORATORIES, INC.

Defendants,

CASE NUMBER: 3:22-cv-635

COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

1. This action arises out of the injuries suffered by Plaintiff's minor protected person who, as a premature infant, was fed Defendants' cow's-milk-based infant formula and/or fortifier and developed Necrotizing Enterocolitis as a result of those feedings. Necrotizing Enterocolitis (hereinafter "NEC") is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut. Advanced cases of NEC

may lead to surgery and to death. Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights who are fed cow's milk-based formula or fortifier products. The companies who manufacture these products often intentionally mislabel and misrepresent the contents of the products both to the public at-large and to the health care community, passing off these deadly products as something similar to or even superior to human breast milk. Kyli Johnson (hereinafter "Kyli"), who was premature at birth, was fed these cow's milk-based products, developed NEC, and sustained significant injuries as a result.

PARTIES

2. Nancy Doty, Inc. ("NDI" and/or Plaintiff) is an Oregon corporation that performs professional fiduciary services for minors and incapacitated adults. The Oregon Circuit Court for Polk County appointed NDI as Conservator for Kyli for the purpose of pursing legal claims against Defendants.

3. Kyli was born prematurely at Oregon Health & Science University in Portland, Oregon on May 20, 2012. Kyli developed NEC after being fed Similac Milk-Based Products while in the Newborn Intensive Care Unit ("NICU") at Doernbecher Children's Hospital in Portland, Oregon. At all times material hereto, Kyli was and is domiciled in and is a citizen of the State of Oregon and is a resident of Polk County. At all times material hereto, Sarah Johnson, the mother of Kyli, (hereinafter "Kyli's Mother"), was and is domiciled in and is a citizen of State of Oregon and is a resident of Polk County.

4. Defendant Abbott Laboratories is a corporation organized under the laws of the State of Illinois with its principal place of business in Illinois. It is the parent company of its wholly owned subsidiary, Defendant Abbott Laboratories, Inc. At all times material to this Complaint, Abbott Laboratories has, and continues to, transact substantial business in Oregon.

5. Defendant Abbott Laboratories, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business in Illinois and is a wholly owned subsidiary of Defendant Abbott Laboratories. At all times material to this Complaint, Abbott Laboratories, Inc. has, and continues to, transact substantial business in Oregon.

6. On information and belief, for all purposes relevant to this Complaint, Abbott Laboratories and Abbott Laboratories, Inc. functioned as one entity, so this Complaint will refer to the Defendants collectively as "Defendants" and/or "Abbott."

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated in and have their principal places of business in states other than the state in which the named Plaintiff resides.

8. Venue in this District is appropriate on the basis that plaintiff NDI is an Oregon corporation with its principal place of business within the geographical boundaries of the United States District Court for the District of Oregon, and defendants have, and continue to, transact substantial business in Oregon.

TAG-ALONG ACTION

9. This is a potential tag-along action and in accordance with 28 U.S.C. §1407, it should be transferred to the United States District Court for the Northern District of Illinois for inclusion in *In re: Abbott Laboratories, et al., Preterm Infant Nutrition Products Liability Litigation,* MDL 3026, (Hon. Rebecca Pallmeyer).

BACKGROUND FACTS RELATED TO NEC CAUSED BY COW'S MILK BASED FORMULAS AND/OR FORTIFIERS

10. According to the World Health Organization ("WHO"), babies born prematurely, or "preterm," are defined as being born alive before 37 weeks of pregnancy are completed, like Kyli. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

11. Nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams), is significantly important. Since the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

12. Science and research confirm strong links between cow's milk-based products and NEC causing and/or substantially contributing to death in preterm and severely preterm, low-weight infants, along with many other health complications and long-term risks to these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-cow's milk-based products, however, the manufacturers of the Cow's Milk-Based Products continue to promote and sell the Cow's Milk-Based Product versions for feeding preterm babies.

13. As far back as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was six to ten times more common in exclusively formula-fed babies than in those fed breast milk alone and three times more common than in those who received formula plus breast milk. The study also found that NEC was rare in babies born at more than 30 weeks gestation whose diet included breast milk, but was 20 times more common in those fed cow's milk-based formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990) (emphasis added).

14. A study published in 2009 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. The results show that preterm babies fed an exclusively human milk-based diet were 90% less likely to develop surgical NEC as compared to a diet that included some cow's milk-based products. S. Sullivan, *et al*, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010) (emphasis added).

15. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)." U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p.1, (2011) (emphasis added). This same report stated that premature infants who are not breast-fed are 138% more likely to develop NEC. *Id*.

16. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of Cow's Milk-Based Products. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk... If the mother's own milk is unavailable ...pasteurized donor milk should be used." *Breastfeeding and the Use of Human Milk*, PEDIATRICS, 129:e827-e84l (2012).

17. Further, a study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk based diet exceeded targeted growth standards and length and weight and head circumference gain. The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving

an exclusive human milk-based diet." A. Hair, *et al*, *Human Milk Feeding Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013) (emphasis added). Thus, inadequate growth was proven to be a poor excuse for feeding Cow's Milk-Based Formula, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula such as the Defendants.

18. Another study published in 2013 reported the first randomized trial in extremely premature infants of exclusive human milk versus preterm cow's milk-based formula. The study found a significantly higher rate of surgical NEC in infants receiving the cow's milk-based preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU. E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013) (emphasis added).

19. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with significant morbidity and mortality. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, *et al*., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July) (emphasis added). The same study found that NEC "is the most frequent and lethal gastrointestinal disorder affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. *Id.* The study noted that "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. *Id.* The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and up to 30%

of infants will die from this disease." *Id.* Advances in formula development have made it possible to prevent necrotizing enterocolitis, and the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id.*

20. In yet another study published in 2014 it was reported that an exclusive human milk diet, devoid of Cow's Milk-Based Products, was associated with "lower mortality and morbidity" in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al*., *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286 (2014).

21. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an exclusive human milk diet is associated with "significant benefits" for extremely preterm infants and while evaluating the benefits of using an exclusive human milk-based protocol, "it appears that there were no feeding-related adverse outcomes." Hair, *et al*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet,* BREASTFEEDING MEDICINE, 11-2 (2016) (emphasis added).

22. A publication by the American Society for Nutrition, in 2017, noted that human milk has "been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC." The study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of cow's milk-based preterm infant formula to human milk as to the rate of NEC. Both trials found that an

exclusive human milk diet resulted in a much lower incidence of NEC. While the study noted that cow's milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the cow's milk-based products significantly increase the risk of NEC and death. The study also noted the "exponential" health care costs associated with NEC and noted data from the U.S. from 2011-2012 that showed that the cost of NEC is $180,000 to $198,000 per infant and increases to $313,000 per infant for surgically treated NEC. Further, NEC survivors accrue substantially higher outpatient costs. Jocelyn Shulhan, *et al*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):80-91 (2017) (emphasis added).

23. The WHO and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address concerns over the marketing of breast-milk substitutes. The WHO Director concluded the meeting with the following statement, "In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement." Jules Law, *The Politics of Breastfeeding: Assessing Risk, Dividing Labor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000) (emphasis added).

24. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly ("WHA"), the decision-making body of the world's Member States, developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast-milk substitutes is specifically prohibited: "There should be no advertising or other form of promotion to the general public [of breast milk substitutes]." (emphasis added). In Article 5.2, the Code states that "manufacturers and distributors should not provide, directly or

indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code." In addition, the Code expressly prohibits, "point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales…" *See* Int'l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

25. The World Health Organization's 2018 Status Report on this issue noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status Report states that "a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes," noting that in 2014, the global sales of breast-milk substitutes amounted to US $44.8 billion and "is expected to rise to US $70.6 billion by 2019." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*. Geneva: World Health Org., 2018, p.21 (emphasis added).

26. Recognizing a shift in the medical community towards an exclusive human based diet for preterm infants, the Defendants began heavily promoting "human milk fortifiers," a name which misleadingly suggests that the product is derived from human milk, instead of being derived from Cow's Milk.

27. Defendants have designed competing, systematic, powerful, and misleading marketing campaigns to persuade physicians and parents to believe that: (1) Cow's Milk-based formula and fortifiers are safe; (2) Cow's Milk-Based Products are equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow's Milk-Based Products a first choice. Similarly, the Defendants markets their products for preterm infants as necessary for growth, and perfectly

safe for preterm infants, despite knowing of the extreme risks posed by Cow's Milk-Based Products and failing to warn of the deadly disease of NEC.

28. Thus, despite the existence of alternative and safe human milk-based fortifiers, Defendants continue to market and/or sell the Cow's Milk-Based Products under the guise of being a safe product for newborns and despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants like Kyli.

29. Defendants promote the use of its preterm infant Cow's Milk-Based Products to parents, physicians, hospitals, and medical providers as safe products that are specifically needed by preterm infants for adequate growth.

30. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's Milk-Based Products, including the significant risk of NEC, Defendants did not warn Kyli's mother or other parents or medical providers of the risk of NEC in preterm infants, nor did Defendants provide any instructions or guidance on how to properly use its Cow's Milk-Based Products so as to lower the risk or avoid NEC.

31. In fact, Defendants did not provide any warning in its labeling, websites, or marketing that warns that its Cow's Milk-Based Products exponentially increase the risk of NEC in preterm infants, or that human breast milk, donor breast milk, and human breast milk-based formulas and fortifiers are much safer for preterm babies than its Cow's Milk-Based Products.

FACTS RELATED TO KYLI BEING FED DEFENDANTS' COWS MILK BASED PRODUCTS

32. Kyli was born prematurely, at 28 weeks gestation, at Oregon Health & Science University in Portland, Oregon on May 20, 2012. At birth, Kyli weighed 1,020 grams (2 lbs 4 oz).

33. After she was born, Kyli was sent to the NICU at Doernbecher Children's Hospital in Portland, Oregon.

34. Following her birth, Kyli's was started on trophic[1] feeds while the mother began to successfully pump her own breast milk for her baby's nutrition.

35. Trophic feeds were stopped on June 4, 2012 and the NICU began feeding Kyli her mother's breastmilk fortified with Similac® NeoSure Infant Formula.

36. On June 11, 2012, Kyli underwent a blood transfusion and it was noted that her abdomen was more distended. An abdominal x-ray was performed, which was concerning for NEC. She was subsequently started on broad spectrum antibiotics.

37. Kyli was diagnosed with NEC on June 12, 2012, and treated medically with Vancomycin, gentamicin and flagyl for 14 days. She was started back on feeds of breastmilk, which was again fortified with Similac® NeoSure Infant Formula. On July 1, 2012, Kyli developed abdominal distension, vomiting (bloody at times) and increased residuals. Abdominal x-rays showed significant strictures (at hepatic and splenic flexures), as well as narrowing of her entire transverse colon. Kyli was taken for exploratory laparotomy and ileostomy placement on July 9, 2012. She was found to have significant adhesions and inflammation, as well as two walled off perforations and spillage of stool into her abdomen. During the procedure, Kyli's vital signs became unstable, so the surgeons opted to place a diverting ileostomy and not do further resection. She was discharged from the hospital on August 8, 2012 with the ostomy in place.

38. Just over four months later, at six and one-half months of age, Kyli underwent an exploratory laparotomy. During this procedure her surgeon performed extensive lysis of adhesions. Kyli underwent ascending, transverse and descending colectomy; ilecocolic anastomosis; and closure of parastomal hernia. Kyli had significant inflammation and oozing was occurring

[1] Trophic feeding is the practice of feeding minute volumes of enteral feeds (tube feeding which delivers nutrients directly to the stomach or small intestines) in order to stimulate the development of the immature gastrointestinal tract of the preterm infant.

throughout her abdomen. There were two areas that appeared to be very strictured and stuck within her colon. One of these was at the splenic flexure and one was in the ascending colon. Both questionably had localized, contained areas of leakage. Both of these areas were showing evidence of perforation and leakage as the surgeon was dissecting them free from the surrounding adhesions. That complicated surgery took place on December 11, 2012 and Kyli remained hospitalized until December 19, 2012. She continues to have frequent and loose stools, difficulty gaining weight and suffers ongoing and permanent bowel incontinence.

39. At the time Kyli was diagnosed with NEC, Kyli's mother was unaware of the fact that the Defendants' Cow's Milk-Based Products she was fed caused or substantially contributed to her development of NEC and resulting injuries. Less than two years before this Complaint was filed, Kyli's mother learned that Defendants' conduct injured Kyli.

COUNT I: STRICT LIABILITY
DESIGN DEFECT

40. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

41. At all times material to this action, Defendants were engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's Milk-Based Products, which are defectively designed and/or unreasonably dangerous to consumers, including Kyli.

42. Defendants, as manufacturers, have a duty to hold expert knowledge and skill and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

43. At all times material to this action, the Cow's Milk-Based Products manufactured, distributed and/or sold by Defendants, were in a defective and/or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

44. Defendants specifically marketed and created its Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants, like Kyli.

45. Defendants Cow's Milk-Based Products are expected to reach the user without substantial change affecting that defective and/or unreasonably dangerous condition and Defendants' product reached Kyli without any substantial change affecting the products.

46. Prior to Kyli's birth, Defendants were aware or should have been aware that its Cow's Milk-Based Products were not safe for use, as they were used, with nutrition or nutritional support in preterm infants, yet took no steps to prevent the use of these products in such situations.

47. Defendants knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products significantly increased the risk of NEC.

48. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC, which far outweighed the products' benefits for preterm infants like Kyli.

49. Despite the foregoing, the Defendants continued to sell and market its defective and/or unreasonably dangerous products to preterm infants.

50. The products were defectively manufactured and/or designed and/or unreasonably dangerous, including, but not limited to the following particulars:

a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, because the use of Cow's Milk-Based Products as nutrition or nutritional supplements in preterm infants, including Kyli, significantly increased the risk of NEC;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, including Kyli, to risks of serious bodily injury;

c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;

d. Defendants failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;

e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;

f. Defendants failed to adopt an adequate or sufficient quality control program; and/or

g. Defendants failed to inspect or test its products with sufficient care.

51. Defendants' defective and unreasonably dangerous products were a substantial contributing cause of Kyli's injuries and damages as alleged herein.

COUNT II: STRICT LIABILITY
FAILURE TO WARN

52. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

53. Defendants, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Kyli, Plaintiff's minor protected person in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

54. Defendants, as the manufacturer and/or seller of Cow's Milk Product, was unreasonable in relying solely upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in its Cow's Milk-Based Products, as the magnitude of the risk involved is using Defendants' Cow's Milk-Based Products with preterm infants is significant and involves the real danger of serious bodily injury.

55. Nonetheless, Defendants, as the manufacturer and/or seller of Cow's Milk Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers of its Cow's Milk-Based Products.

56. Defendants owed a duty to provide warnings and instructions on its Cow's Milk-Based Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care providers and staff using these products in a NICU, taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

57. Rather than provide adequate warnings, Defendants developed relationships which included incentives and financial gain to health care providers and facilities for using its Cow's Milk-Based Products within the NICU.

58. In addition, and/or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's Milk-Based Products with preterm infants, they would have not used such a dangerous product.

59. Defendants, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

60. Defendants, through its own testing and studies, consultants and experts, and/or knowledge of the scientific literature, knew, or should have known, of the significant risk of NEC with preterm infants.

61. Defendants, through its knowledge, review, and survey of the scientific literature, knew, or should have known, that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to NEC.

62. Defendants failed to provide proper warnings and/or instructions of its Cow's Milk-Based Products, including but not limited to the following acts:

a. Providing no warnings regarding the risk of NEC;

b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products with preterm infants, including but not limited to NEC;

c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC;

d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendant's Cow's Milk Product;

e. Failed to provide instructions to consumers and health care providers that the Defendants' products carried a significant risk that its Cow's Milk-Based Products exponentially increased their baby's risk of developing NEC;

f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn that the use of Cow's Milk-Based Products significantly increasing the risk of NEC, and they fail to provide any details on how to avoid such harm;

g. Failed to provide well researched and well-established studies that linked its Cow's Milk-Based Products to NEC in preterm infants;

h. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its products;

i. Failed to otherwise warn physicians, and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;

j. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or

k. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants.

63. Defendants' defective and unreasonably dangerous products were a substantial contributing cause of Kyli's injuries and damages as alleged hereinafter.

COUNT III NEGLIGENCE

64. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

65. Defendants, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and to Kyli, Plaintiff's minor protected person in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute products free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

66. Defendants, as manufacturers, have a duty to hold the knowledge and skill of an expert, and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

67. Defendants, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed and/or sold the subject Cow's Milk-Based Products.

68. Defendants were negligent in that they created a foreseeable, unreasonable risk of harm to preterm infants, including Kyli, who were fed their Cow's-Milk based formulas and/or fortifiers in one or more of the following ways:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury from NEC;

c. Failing to collect and properly analyze data to determine if its products were safe for preterm infants;

d. Failing to collect and properly analyze data to determine when and how its products could be used safely;

e. Failing to utilize the significant peer reviewed research to develop instructions for use of its products;

f. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC;

g. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC;

h. Failing to stop or deter its products from being fed to extremely preterm infants;

i. Promoting the use of its products to be fed to extremely preterm infants;

j. Failing to provide evidence-based instructions or guidance on when or how a preterm infant should be transitioned to their Cow's-Milk based products;

k. Failing to continuously and vigorously study its cow's milk-based products in order to avoid NEC in premature infants;

l. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;

m. Failing to adopt an adequate or sufficient quality control program; and/or

n. Failing to inspect or test its products with sufficient care.

69. Defendants knew or should have known that its products were to be used as nutrition and nutritional supplements with preterm infants, including Kyli.

70. Defendants knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products significantly increased the risk of NEC.

71. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC, which far outweighed the products' benefits for premature infants including Kyli.

72. Defendants' negligence in one or more of the ways alleged herein was a substantial contributing factor causing the injuries and damages sustained by Kyli as alleged herein.

IV. VIOLATION OF OREGON UNLAWFUL TRADE PRACTICES ACT AND/OR VIOLATION OF ILLINOIS CONSUMER FRAUD A ND DECEPTIVE BUSINESS PRACTICES ACT

73. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

74. Defendants' actions as alleged above, including asserting that their products had characteristics they did not have and defendants' actions in failing to inform the public including plaintiff and Kyli of defects in their product, constituted deceptive acts or deceptive practices; defendant intended for plaintiff and Kylie to rely on defendants deception; the deception occurred in the course of Abbott business trade and commerce; & defendants deceptive acts were

the proximate cause of Kyli' injuries and damages alleged herein.

75. What for defendants deceptive actions and or unlawful trade practices and representations, plaintiff and Kylie with that have used defendants Products and Kyle would not have been injured and sustained damages from the use of those products.

76. Plaintiff is entitled to recover reasonable attorney fees and costs pursuant to Oregon's UTPA and/or Illinois' ICFA.

V. DAMAGES ALLEGATION

77. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

78. Defendants' actions as alleged herein were a substantial contributing factor in causing Kyli's injuries and damages described throughout this Complaint including those injuries described in ¶ ¶37-38. Kyli has sustained permanent physical injuries, surgery to remove part of her colon, extensive lysis of adhesions, the permanent inability to control her bowel movements, pain, agony, interference with her normal life activities, sleeplessness, worry, embarrassment, humiliation, fear of future need for surgeries and medical expenses past and future. These damages will be proven at trial and exceed $75,000.00.

VI. PUNITIVE DAMAGES

79. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

80. Defendants' conduct as alleged above was taken in wanton disregard for the health safety and well-being of the public, including Plaintiff's protected minor Kylie. Defendants acted intentionally and or with reckless disregard for the consequences of their actions on the public and Plaintiff's protected minor Kylie.

81. Defendants' actions are sufficiently egregious to warrant the imposition of punitive damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

1. For compensatory damages in an amount to be proven at trial;

2. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, loss of consortium, and other non-economic losses sustained as a result of Defendants' conduct;

3. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

4. For punitive damages as proven at trial;

5. For attorney's fees, expenses, and recoverable costs incurred in connection with this action, interest as permitted by law; and

6. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury on all issues triable by jury.

DATED this 29th day of April, 2022.

BOWERSOX LAW FIRM, P.C.

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